STATE OF INDIANA	) ) SS:	IN THE MARION CIRCUIT COURT	
COUNTY OF MARION	) 33.	AVC NO.	<u>04-026</u>
IN THE MATTER OF:			
WARNER-LAMBERT COMPANY, LLC,			FILED
	Respondent.	(32)	MAY 1 3 2001
			MARION CIRCUIT COURT

# ASSURANCE OF VOLUNTARY COMPLIANCE

APPROVED this \_\_\_\_\_ day of May, 2004.

Judge, Marion County Circuit Court

# IN THE MATTER OF WARNER-LAMBERT COMPANY LLC

#### ASSURANCE OF VOLUNTARY COMPLIANCE

This Assurance of Voluntary Compliance ("Assurance") is entered into between the Attorneys
General of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District
of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana,
Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska,
Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio,
Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas,
Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin and Wyoming ("Signatory Attorneys
General"), <sup>1</sup> acting pursuant to their respective consumer protection statutes, and Warner-Lambert
Company LLC, successor to Warner-Lambert Company (hereinafter referred to as "Warner-Lambert").

#### I. DEFINITIONS

The following definitions shall be used in construing this Assurance:

<sup>&</sup>lt;sup>1</sup> For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys General," such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Assurance of Voluntary Compliance pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel, Richard Blumenthal, Attorney General for the State of Connecticut. The chief legal officer of the DISTRICT OF COLUMBIA is the Corporation Counsel, who for uniformity shall also be referred to as "Attorney General." With regard to GEORGIA, the Administrator of the Fair Business Practices Act, appointed pursuant to O.C.G.A. Section 10-1-395, is statutorily authorized to undertake consumer protection functions, including the acceptance of Assurances of Voluntary Compliance, for the State of Georgia. The term "Attorneys General" as used herein, as it pertains to Georgia, refers to the Administrator of the Fair Business Practices Act. With regard to HAWAII, Hawaii is represented by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to represent the State of Hawaii in consumer protection actions. Hereafter, when the entire group is referred to as the "States" or "Attorneys General," such designation as it pertains to Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection. For MONTANA, the acting agency is the Consumer Protection Office.

- A. "Signatory Attorney General" shall mean the Attorney General of each state in the Multistate Working Group investigating Neurontin, or his or her designee.
- B. "Covered Persons" shall mean all current and future officers, employees and agents of
   Warner-Lambert having direct responsibility for marketing and promoting Neurontin to prescribers.
- C. "Advertising Subaccount" shall mean a subaccount that shall finance the National Advertising Program to be administered by the MSEC.
  - D. "Compliance Provisions" shall mean Paragraphs 6 through 19 of this Assurance.
- E. "Effective Date" shall mean the date on which Warner-Lambert receives a copy of this Assurance, duly executed by Warner-Lambert and by each Signatory Attorney General.
- F. "Individual State" and "State" shall mean each Signatory Attorney General who is participating in the Multistate Working Group.
- G. "Multistate Working Group" ("MSWG") shall mean the Attorneys General and their staffs representing the states of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.
- H. "Multistate Executive Committee" ("MSEC") shall mean a committee of the MSWG composed of the representatives of the Attorneys General from Florida, New York, Ohio, Oregon, Texas and Vermont.

- "National Advertising Program" shall mean a program designed to provide to prescribers information relating to Neurontin and other drugs in the same therapeutic class.
  - J. "Neurontin" or the "Product" shall mean gabapentin.
- K. "Off-Label Use" shall mean any indication that has not been approved by the U.S. Food and Drug Administration.
  - L. "Parties" shall mean Warner-Lambert and the Individual States.
- M. "Prescriber and Consumer Education Program" shall mean national programs, regional programs, and programs in individual states or in a group of states, funded by the Settlement Fund, relating to prescriber and consumer education regarding drug information, drug marketing, and the conditions for which drugs are prescribed.
- N. "Prescriber and Consumer Education Subaccount" shall mean a subaccount that shall finance the Prescriber and Consumer Education Program.
- O. "Settlement Account" shall mean a new interest bearing account secured and maintained by the State of Oregon used to hold and administer the Settlement Fund.
- P. "Settlement Fund" shall mean the amount of twenty-eight million U.S. dollars (\$28,000,000.00) required to be paid pursuant to this Assurance.
- Q. "Special Committee" shall mean the Attorneys General, or their authorized designees, that comprise the MSEC plus two Attorneys General, or their authorized designees, from the remaining members of the MSWG which shall be selected on a biannual rotating basis, in the first instance by the Attorneys General of the MSEC and thereafter by the Attorneys General represented on the Special Committee.

R. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Attorneys General have conducted their investigation.<sup>2</sup>

ALABAMA - Deceptive Trade Practices Act, Ala. Code § 8-19-1 et seq.; ALASKA - Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 through 45.50.561 et seq.; ARIZONA -Consumer Fraud Act, A.R.S. § 44-1521 et seq.; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 et seq.; CALIFORNIA - Bus. & Prof. Code §§ 17200 et seq., and 17500 et seq.; COLORADO - Colorado Consumer Protection Act, C.R.S. §§ 6-1-101 et seq.; CONNECTICUT — Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110 et seg.; DELAWARE - Consumer Fraud Act, 6 Del.C. Section 2511, et seq., UDTPA, 6 Del.C. Section 2531, et seq.; DISTRICT OF COLUMBIA - Consumer Protection Procedures Act, D.C. Official Code § 28-3901 et seq.; FLORIDA Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 et seq.; GEORGIA - Fair Business Practices Act of 1975, O.G.C.A. § 10-1-390 et seq.; HAWAII – Haw. Rev. Stat. § 480-2; IDAHO -Consumer Protection Act, Idaho Code § 48-601 et seq.; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 et seq. (2002); INDIANA - Deceptive Consumer Sales Act, Indiana Code 24-5-0.5-1 et seq.; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-623, et seq.; KENTUCKY - Consumer Protection Statute, KRS 367.170; LOUISIANA - LSA-R.S. 51:1401, et. seq; MAINE - Unfair Trade Practices Act, 5 M.R.S.A. section 205-A et. seq; MARYLAND - Consumer Protection Act, Maryland Commercial Law Code Annotated § 13-101 et seq.; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A et seq.; MICHIGAN - Consumer Protection Act, Mich. Comp. Laws §445.901 et seq. (2004); MINNESOTA - Minn. Stat. secs. 8.31; 325F.67; 325F.69; MISSISSIPPI - Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq.; MISSOURI - Missouri Merchandising Practices Act, Missouri Revised Statutes Section 407.010 et. seq.; MONTANA - Mont. Code Ann. § 30-14-101 et seq.; NEBRASKA - CPA Neb.Rev.Stat.59-1601, et seq (Reissue 1999 & Cum Supp. 2002)) & UDTPA, Neb.Rev.Stat. 87-301 et. seq. (Reissue1999 & Cum Supp. 2002); NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE – RSA 358-A:2; NEW JERSEY - Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.; NEW MEXICO - Unfair Trade Practices Act, NMSA § 57-12-1 et seq. (1978); NEW YORK - N.Y. Gen. Bus. Law §§ 349 & 350 and Executive Law § 63(12); NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 et seq.; NORTH DAKOTA - Consumer Fraud and Unlawful Credit Practices N.D.C.C. § 51-15-01 et seq.; OHIO - Consumer Sales Practices Act, R.C. § 1345.01 et seq.; OKLAHOMA - 15 O.S. sections 751 et seq.; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 et seq.; RHODE ISLAND - Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws § 6-13.1-1, et seq.; SOUTH CAROLINA - Unfair Trade Practices Act, Sections 39-5-10 et seq.; SOUTH DAKOTA SDCL § 37-24-1 through 40 et seq.; TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 et seq., (1977); TEXAS - Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 et seq., (Vernon 2002); UTAH - Consumer Sales Practices Act, §13-11-1 et seq.; Truth In Advertising Act, §13-11a-1 et seq.; VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 et seq.; VIRGINIA - Virginia Consumer Protection Act, 59.1 -196 et seq.; WASHINGTON -Unfair Business Practices/Consumer Protection Act, R.C.W. 19.86 et seg.; WEST VIRGINIA - Code Section 46A-1-101 et seq.; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations); WYOMING -W.S. §§ 40-12-102 et seq.

- S. "Subject Matter of this Assurance" shall mean the Signatory Attorneys' General investigation under the State Consumer Protection Laws of Warner-Lambert's promotional and marketing practices regarding the Off-Label Use of Neurontin.
- T. "Warner-Lambert" shall mean Warner-Lambert Company LLC, its affiliates, subsidiaries, predecessors, successors, parents and assigns who manufacture, sell, distribute and/or promote Neurontin.

#### II. BACKGROUND

- Warner-Lambert is in the business of researching, developing, manufacturing, distributing and promoting drugs for use in treating various illnesses and diseases.
- Neurontin, a prescription drug, is approved by the FDA as safe and effective in adjunctive treatment for epilepsy and in the treatment of post-herpetic neuralgia.
- 4. The States have concerns that Warner-Lambert Company, the predecessor of Warner-Lambert Company LLC, has engaged in certain promotional and marketing practices for Off-Label Uses of Neurontin, and in particular that those promotional and marketing practices violated the State Consumer Protection Laws.
- 5. Warner-Lambert does not admit any violation of the State Consumer Protection Laws.
  Warner-Lambert enters into this Assurance for the purpose of resolving the Signatory Attorneys'
  General inquiry into Neurontin promotional and marketing practices, arriving at a complete and total settlement and resolution of any disagreement as to the matters addressed in this Assurance to avoid unnecessary expense, inconvenience, and uncertainty, without admitting any violation of law and without admitting any wrongdoing, and for settlement purposes only.

#### III. COMPLIANCE PROVISIONS

 Warner-Lambert shall not make any written or oral claim that is false, misleading or deceptive regarding the Product.

- Warner-Lambert shall not make any written or oral promotional claim of safety or effectiveness for the Product for Off-Label Uses in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), and accompanying regulations.
- 8. Warner-Lambert shall not provide to health care professionals written materials describing the Off-Label Use of the Product that have not appeared in a scientific or medical journal or reference publication or any portion thereof, except upon an independent request for such information, without solicitation by Warner-Lambert to make the request. Warner-Lambert shall maintain records for three years of the identity of all health care professionals to whom such materials relating to the Off-Label Use of the Product have been provided. "Scientific or medical journal" is a publication whose articles are peer-reviewed and published in accordance with regular peer-reviewed procedures; that uses experts to review or provide comment on proposed articles; and that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers. "Reference publication" is a publication that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer; that has not been written, edited, excerpted, or published specifically for, or at the request of, such a manufacturer; and that has not been edited or significantly influenced by such a manufacturer.
- 9. A. When Warner-Lambert provides an individual with any educational grant, research grant, or other similar remuneration relating to the Product, Warner-Lambert shall obtain the recipient's agreement to clearly and conspicuously disclose the existence of said remuneration to the readers of any letter, study, research or other materials which was funded by said remuneration, and to refund said remuneration if such disclosure is not made.
- B. Warner-Lambert shall require that a recipient of any remuneration from Warner-Lambert relating to the promotion of the Product agree to clearly and conspicuously disclose, both

orally and in writing as part of any prepared presentation materials, the existence, nature and purpose
of the remuneration to the participants in any educational event at which the recipient discusses an OffLabel Use of the Product, and to refund said remuneration if such disclosure is not made.

- C. Warner-Lambert shall itself clearly and conspicuously disclose the existence of any grant or other form of remuneration that it has provided for the publication of a letter, study, research or other material relating to the Product when Warner-Lambert disseminates or refers to said letter, study, research or other material in communications with health care professionals.
- 10. In addition to the requirements set forth in paragraphs 6 19 herein, Warner-Lambert shall comply with the relevant Accreditation Council for Continuing Medical Education Guidelines with respect to participation in educational events relating to the Product.
- Warner-Lambert shall not misrepresent the nature of any promotional, educational or research event relating to the Product.
- 12. In addition to the requirements set forth in paragraphs 6 19 herein, Warner-Lambert shall comply with paragraphs 2, 3, 4, 5, 7 and 8 of the Pharmaceutical Research and Manufacturers of America Code (effective on July 1, 2002) with respect to payments, gifts and other remuneration to health care providers regarding the Product.
- 13. Warner-Lambert shall not misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to Off-Label Uses of the Product. In any discussion of the Off-Label Uses of the Product, any information provided by Warner-Lambert shall not be misleading or lacking in fair balance, as defined in 21 CFR §202.1.
- 14. Warner-Lambert shall not misrepresent, in any written or oral claim relating to the Product that its sales, medical or technical personnel have experience or credentials or are engaging in

research activities if they do not in fact possess such credentials or experience, or are not engaging in such activities.

- Warner-Lambert shall comply with the federal anti-kickback statute, 42 U.S.C.
   §1320a7, with respect to its relationship with any physician or other health care provider relating to the Product.
- If Warner-Lambert provides information about the Product to Drugdex or any other reference compendium, the information shall not be misleading or lacking in fair balance, as defined in 21 CFR §202.1.
- 17. The obligations of Warner-Lambert under this Assurance shall be prospective only. No Signatory Attorney General shall institute any proceeding or take any action against Warner-Lambert under its State Consumer Protection Laws or any similar state authority, or under this Assurance, based on Warner-Lambert's prior promotional or marketing practices for Neurontin.
  - Nothing in this Assurance shall require Warner-Lambert to:
  - take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or
  - (b) fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this Assurance which is the same or substantially the same as the language prescribed by FDA in the Neurontin package insert, and which accurately portrays the data or other information referenced in the Neurontin package insert, shall not constitute a violation of this Assurance.

#### Warner-Lambert shall:

(a) within 90 days after the Effective Date of this Assurance, institute compliance procedures which are designed to begin training those Warner-Lambert officers and employees whose responsibilities or duties include compliance with this Assurance, about how to comply with this Assurance;

- (b) submit to each Signatory Attorney General, within 120 days after the Effective
   Date of this Assurance, a written description of such training; and
- (c) submit to each Signatory Attorney General, one year after the Effective Date of this Assurance, a written affirmation setting forth Warner-Lambert's compliance with this paragraph.
- (d) for a period of three (3) years from the Effective Date of this Assurance, Warner-Lambert shall provide a copy of Paragraphs 6 through 18 of this Assurance to all current and future officers, employees and agents having direct responsibility for marketing and promoting the Product ("Covered Persons").

#### IV. SETTLEMENT FUND

20. Within thirty days of the Effective Date of this Assurance, Warner-Lambert shall pay the amount of twenty-eight million U.S. dollars (\$28,000,000.00) (the "Settlement Fund") to the States by electronic funds transfer, or certified or cashier's check, made payable to the Oregon Department of Justice and shall be tendered to the State of Oregon to be held in a new interest bearing account (the "Settlement Account"), created for the benefit of the Multistate Working Group ("MSWG"), the monies of which shall be used for the purposes delineated in Paragraphs 20 through 32 pursuant to the terms of this Assurance, and shall be administered pursuant to the Order attached as Exhibit A (the "Order"). Warner-Lambert and the Signatory Attorneys General stipulate that the Oregon Attorney General shall submit the Order to the Marion County Circuit Court concurrently with the submission

of this Assurance.<sup>3</sup> The Settlement Fund, and interest generated therefrom, shall not be commingled with other funds, and shall be administered pursuant to the Order.

21. Upon payment of the Settlement Fund in the manner prescribed in Paragraph 20 of this Assurance, and upon further payment to the Signatory Attorneys General as prescribed in Paragraph 33, Warner-Lambert shall (a) be fully divested of any interest in, or ownership of, the monies paid and all interest in the monies, and any subsequent interest or income derived therefrom shall inure entirely to the benefit of MSWG, pursuant to the terms of this Assurance; (b) have no further obligation to make any payment to the Signatory Attorneys General, pursuant to this Assurance; (c) have no control over, responsibility for or input as to the disbursement of any funds or designation of any funds; and (d) have no further obligation to the Signatory Attorneys General, pursuant to Paragraph 20 and Paragraph 33 of this Assurance.

## V. <u>DISBURSEMENT OF PAYMENTS:</u> NATIONAL ADVERTISING PROGRAM

- 22. A portion of the Settlement Fund, in the amount of six million U.S. dollars (\$6,000,000.00), shall be paid from the Settlement Account for use by the MSEC to develop the National Advertising Program on behalf of the MSWG. The fund subaccount that shall finance the National Advertising Program shall be known as the Advertising Subaccount. Such fund shall be administered by the MSEC.
- 23. The National Advertising Program shall provide information to prescribers regarding Neurontin and other drugs in the same therapeutic class, including, but not limited to, by placing advertisements in medical journals.

<sup>&</sup>lt;sup>3</sup> Warner-Lambert and the Signatory Attorneys General further stipulate that the Signatory Attorneys General may substitute Exhibit A with the Order signed and entered by the Marion County Circuit Court upon said Court's approval.

- 24. The MSEC may retain experts and other vendors, including advertising agencies, from the monies in the Advertising Subaccount to assist in the drafting, design and implementation of the National Advertising Program on behalf of the MSWG.
- Any advertisement or other public communication regarding Neurontin prepared in connection with the National Advertising Program shall not be misleading or lacking in fair balance, as defined in 21 CFR §202.1.
- 26. At the conclusion of the National Advertising Program, as determined by the MSEC, any portion of the monies provided for in Paragraph 20 of this Assurance that are not expended in the National Advertising Program, pursuant to Paragraphs 22 through 25, shall be transferred to the Prescriber and Consumer Education Subaccount created pursuant to Paragraphs 27 29, below.

## VI. <u>DISBURSEMENT OF PAYMENTS:</u> PRESCRIBER AND CONSUMER EDUCATION GRANTS

- 27. A portion of the Settlement Fund, in the amount of twenty-one million U.S. dollars (\$21,000,000.00), shall be paid from the Settlement Account for use by the MSWG in funding national programs, regional programs, or programs in individual states or in a group of states, relating to prescriber and consumer education regarding drug information, drug marketing, and the conditions for which drugs are prescribed ("Prescriber and Consumer Education Program"). The Settlement Fund subaccount that shall finance the Prescriber and Consumer Education Program shall be known as the Prescriber and Consumer Education Subaccount, and shall be administered by the Special Committee on behalf of the MSWG.
- 28. The Prescriber and Consumer Education Program shall make grants available to Individual States or a group of States, or to other governmental entities, academic institutions, or notfor-profit organizations that have current section 501(c)(3) status from the Internal Revenue Service and have expertise and experience in health-related or consumer protection issues, approved by the

Special Committee for the purpose of funding programs designed to educate prescribers and/or consumers relating to drug information, drug marketing, and the conditions for which drugs are prescribed.

29. The Special Committee may retain experts and other vendors from the monies in the Prescriber and Consumer Education Subaccount to assist in developing the criteria for grant applications as well as in reviewing any grant application. The Special Committee shall require in any contract with a grantee of the Prescriber and Consumer Education Program that the grantee possess, with respect to any representation made in a public communication produced in connection with said grant, substantial evidence or substantial clinical experience that substantiates the representation.

# VIII. <u>DISBURSEMENT OF PAYMENTS:</u> EVALUATION AND ADMINISTRATION OF ADVERTISING SUBACCOUNT AND PRESCRIBER AND CONSUMER EDUCATION SUBACCOUNT

- 30. No Individual Signatory Attorney General shall have any claim to the funds in the Advertising Subaccount. Distributions from the Advertising Subaccount shall be made at the discretion of the MSEC, and solely for the purposes outlined in this Assurance.
- 31. No Individual Signatory Attorney General shall have any claim to the funds in the Prescriber and Consumer Education Subaccount. Distributions from the Prescriber and Consumer Education Subaccount shall be made at the discretion of the Special Committee and solely for the purposes outlined in this Assurance.
- 32. A portion of the Settlement Fund, in the amount of one million U.S. dollars (\$1,000,000.00), shall be paid from the Settlement Account into a subaccount created for purposes of evaluating the effectiveness of the National Advertising Program and the Prescriber and Consumer Education Program and of grantees' compliance with the requirements of the Prescriber and Consumer Education Program (the "Evaluation Subaccount"). Funds in the Evaluation Subaccount shall be

administered by the Special Committee. The Special Committee may retain an expert or experts from the Evaluation Subaccount to conduct evaluations of the National Advertising Program and the Prescriber and Consumer Education Program.

## IX. <u>DISBURSEMENT OF PAYMENTS:</u> PAYMENT TO THE STATES

33. Within thirty (30) days of the Effective Date of this Assurance, Warner-Lambert shall pay ten million U.S. dollars (\$10,000,000.00), to be divided and paid by Warner-Lambert directly to each Signatory Attorney General in an amount to be designated by and in the sole discretion of the MSWG, as part of the consideration for the termination of their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Assurance. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.<sup>4</sup>

<sup>4</sup> For ALASKA, said payment shall be used at the discretion of the Attorney General for consumer protection and antitrust investigation, enforcement, and education. In ARKANSAS, the money shall be placed in the Arkansas Attorney General's Consumer Education and Enforcement Fund and held in trust for purposes directly related to Arkansas consumer protection efforts. For COLORADO, such funds, along with interest thereon, shall be held in trust by the Attorney General and shall be used first for reimbursement of the Attorney General's actual costs and attorney fees and second, for consumer education and for consumer and/or antitrust enforcement efforts. DELAWARE'S payment will go to the Consumer Protection Fund. With respect to the State of GEORGIA, said payment shall be used for the reimbursement of costs, including monitoring of compliance, and any remainder, at the end of thirty-six (36) months, shall be delivered to the Georgia Consumer Preventative Education Plan pursuant to O.G.C.A. §10-1-381. In MASSACHUSETTS, the money shall be deposited into the Local Consumer Aid Fund pursuant to M.G.L. c. 12, section 11G. In OREGON, the money shall be deposited to the Consumer Protection and Education Revolving Account established pursuant to ORS 180.095. In PENNSYLVANIA, funds distributed to the Pennsylvania Office of Attorney General may be used for costs of investigation, attorney fees and for future consumer protection and public protection purposes. In WEST VIRGINIA, the money shall be placed in trust and used at the discretion of the Attorney General solely for consumer protection purposes, including but not limited to, restitution, consumer education, credit or bankruptcy counseling and education, conflict resolution programs, and costs associated with implementing restitution programs.

#### X. GENERAL PROVISIONS

- This Assurance shall be governed by the laws of the above named states.
- 35. This Assurance is entered into by the Parties as their own free and voluntary act and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Assurance.
- 36. Nothing in this Assurance constitutes any agreement by the Parties concerning the characterization of the amounts paid pursuant to this Assurance for purposes of the Internal Revenue Code or any state tax laws.
- 37. This Assurance does not constitute an approval by the Signatory Attorneys General of any of Warner-Lambert's business practices, including its promotional or marketing practices, and Warner-Lambert shall make no representation or claim to the contrary.
- 38. This Assurance sets forth the entire agreement between the Parties hereto and supersedes all prior agreements or understandings, whether written or oral, between the Parties and/or their respective counsel with respect to the subject matter hereof. This Assurance may be amended by written agreement between the Parties, subject to any further requirements under an individual Signatory Attorney General's state law.
- 39. This Assurance may be executed in counterparts, each of which shall be deemed an original, but all of which shall together be one and the same Assurance. This Assurance shall become effective on the Effective Date, which shall be the date on which Warner-Lambert receives a copy of this Assurance, duly executed by Warner-Lambert and by each of the Signatory Attorneys General.<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Warner-Lambert LLC agrees that the Attorney General of Minnesota may file this Assurance and any supporting documents pursuant to Minn. Stat. sec. 8.31 without counsel for Warner-Lambert LLC present.

#### XI. REPRESENTATIONS AND WARRANTIES

- 40. Warner-Lambert warrants and represents that it and its predecessors, successors and assigns manufactured, sold, distributed and promoted the Product. Warner-Lambert further acknowledges that it is a proper party to this Assurance. Warner-Lambert further warrants and represents that the individual signing this Assurance on behalf of Warner-Lambert is doing so in his or her official capacity and is fully authorized by Warner-Lambert to enter into this Assurance and to legally bind Warner-Lambert to all of the terms and conditions of the Assurance.
- Each of the Parties represents and warrants that it negotiated the terms of this Assurance in good faith.
- 42. Each of the Signatory Attorneys General warrants and represents that he or she is signing this Assurance in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Assurance, including but not limited to the authority to grant the release contained in Paragraphs 44 46 of this Assurance, and to legally bind his or her state to all of the terms and conditions of this Assurance.
- 43. Warner-Lambert acknowledges and agrees that the Signatory Attorneys General have relied on all of the representations and warranties set forth in this Assurance and that, if any representation is proved false, unfair, deceptive, misleading, or inaccurate in any material respect, the Signatory Attorney General has the right to seek any relief or remedy afforded by law or equity in the respective state.

#### XII. RELEASE

44. Based on their inquiry into Neurontin promotional practices, the Signatory Attorneys General have concluded that this Assurance is the appropriate resolution of any alleged violations of the State Consumer Protection Laws. The Signatory Attorneys General acknowledge by their execution hereof that this Assurance terminates their inquiry under the State Consumer Protection Laws into Warner-Lambert's promotional practices regarding Neurontin prior to the Effective Date of this Assurance.

- 45. In consideration of the Compliance Provisions, payments, undertakings, and acknowledgments provided for in this Assurance, and conditioned on Warner-Lambert's making full payment of the amounts specified in Paragraph 20 and 33, and subject to the limitations and exceptions set forth in Paragraph 46, each State releases and forever discharges, to the fullest extent permitted by law, Warner-Lambert and its past and present officers, directors, shareholders, employees, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Signatory Attorneys General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Assurance relating to or based upon the Subject Matter of this Assurance ("Released Claims").
- 46. The Released Claims set forth in Paragraph 45 specifically do not include the following claims:
- (a) private rights of action by consumers, provided, however, that this Assurance does not create or give rise to any such private right of action of any kind;
- (b) claims relating to Best Price, Average Wholesale Price or Wholesale Acquisition
   Cost reporting practices or Medicaid fraud or Abuse;
  - (c) claims of antitrust, environmental or tax liability;
  - (d) claims for property damage; and
  - (e) claims to enforce the terms and conditions of this Assurance.

#### XIII. NO ADMISSION OF LIABILITY

- 47. This Assurance does not constitute an admission by Warner-Lambert for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Assurance constitute evidence of any liability, fault, or wrongdoing. Warner-Lambert enters into this Assurance for the purpose of resolving the concerns of the Signatory Attorneys General regarding Warner-Lambert's promotional and marketing practices for Off-Label Uses of Neurontin. Warner-Lambert does not admit any violation of the State Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged by the Signatory Attorneys General.
- 48. This Assurance shall not be construed or used as a waiver or any limitation of any defense otherwise available to Warner-Lambert. This Assurance is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this Assurance, including this paragraph, shall be construed to limit or to restrict Warner-Lambert's right to use this Assurance to assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or future legal or administrative action or proceeding.

#### XIV. DISPUTES REGARDING COMPLIANCE

49. For the purposes of resolving disputes with respect to compliance with this Assurance, should any of the Signatory Attorneys General have legally sufficient cause (which shall include, at a minimum, a reasonable basis to believe that Warner-Lambert has violated a provision of this Assurance) to object to any promotional or marketing practices relating to Neurontin subsequent to the Effective Date of this Assurance, then such Attorney General shall notify Warner-Lambert in writing of the specific objection, identify with particularity the provisions of this Assurance and/or the State Consumer Protection Law that the practice appears to violate, and give Warner-Lambert thirty (30) business days to respond to the notification; provided, however, that a Signatory Attorney General may

take any action upon notice to Warner-Lambert where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

50. Upon giving Warner-Lambert thirty (30) business days to respond to the notification described in Paragraph 49 above, the Signatory Attorney General shall be permitted reasonable access to inspect and copy relevant, non-privileged, non-work-product records and documents in the possession, custody or control of Warner-Lambert that relate to Warner-Lambert's compliance with each provision of this Assurance as to which legally sufficient cause has been shown. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Warner-Lambert.

## XV. PENALTIES FOR FAILURE TO COMPLY

51. The State may assert any claim that Warner-Lambert has violated this Assurance in a separate civil action to enforce this Assurance, or to seek any other relief afforded by law. In any such action or proceeding, relevant evidence of conduct that occurred before the Effective Date shall be admissible on any material issue, including alleged willfulness, intent, knowledge, contempt or breach, to the extent permitted by law. By this Paragraph 51, Warner-Lambert does not waive any evidentiary objection or any other objection it may have as permitted by law to the admissibility of any such evidence.

#### XVI. COMPLIANCE WITH ALL LAWS

- Except as expressly provided in this Assurance, nothing in this Assurance shall be construed as
- (a) relieving Warner-Lambert of its obligation to comply with all state laws, regulations
   or rules, or granting permission to engage in any acts or practices prohibited by such law, regulation or rule; or
  - (b) limiting or expanding in any way any right the State may otherwise have to obtain

information, documents or testimony from Warner-Lambert pursuant to any state law, regulation or rule, or any right Warner-Lambert may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

#### XVII. NOTICES UNDER THIS ASSURANCE

53. Any notices required to be sent to the State or to Warner-Lambert by this Assurance shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For the individual States:

to the addresses listed in Section XVIII.

For the MSWG and MSEC:

Julie Brill
Assistant Attorney General
Office of the Vermont Attorney General
109 State Street
Montpelier, VT 05609-1001

And

David Hart
Assistant Attorney General
Financial Fraud Section, Civil Enforcement
Oregon Department of Justice
1162 Court Street, NE
Justice Building
Salem, OR 97310

For Warner-Lambert:

James Murray, Esq. Davis Polk & Wardwell 450 Lexington Avenue New York, NY 10017

# XVIII. SIGNATURES

#### FOR WARNER-LAMBERT

BY:

Marien Topley

(Signature)

Name:

Martin Teicher

(Printed)

Title:

Vice President

Warner-Lambert Company LLC

Address:

201 Tabor Road, Morris Plains, NJ 07950

Phone No .:

973-385-2000

Date:

May 11, 2004

Approved as to form:

BY:

(Signature)

Name:

James P. Rouhandeh

(Printed)

Davis Polk & Wardwell

Dated: April 1, 2004

TROY KING

Attorney General of the State of Alabama

Leanne L. Fulto

Deanna L. Fults

Assistant Attorney General

Office of the Alabama Attorney General

11 South Union Street

Montgomery, AL 36130

Dated:

GREGG D. RENKES

Attorney General of the State of Alaska

Cynthia C. Drinkwater

Assistant Attorney General

1031 West 4th Avenue, Ste. 200

Anchorage, Alaska 99501

Dated: March 31, 2004

TERRY GODDARD Attorney General of the State of Arizona

Noreen R. Matts

Assistant Attorney General Office of the Arizona Attorney General Consumer Protection & Advocacy Section 400 West Congress, South Building, Suite 315 Tucson, Arizona 85701

Dated: March 29, 2004

MIKE BEEBE

Attorney General of the State of Arkansas

in Male

Benjamin R. McCorkle

Assistant Attorney General

Office of the Arkansas Attorney General

323 Center Street

Little Rock, Arkansas 72201

# In the Matter of WARNER LAMBERT LLC ASSURANCE

DATED: APRIL 1, 2004

BILL LOCKYER, Attorney General of the State of California

ALBERT NORMAN SHELDEN

Acting Senior Assistant Attorney General

Office of the Attorney General 110 West A Street, Suite 1100

P.O. Box 85266

San Diego, California 92186-5266

Dated: April 1, 2004

KEN SALAZAR

Attorney General of Colorado

Jan Michael Zavislan
Deputy Attorney General
Colorado Department of Law
1525 Sherman Street, 5th Floor

Denver, CO 80203

Dated this 31st day of March 2004.

EDWIN R. RODRIGUEZ, COMMISSIONER OF CONSUMER PROTECTION,

BY: RICHARD BLUMENTHAL ATTORNEY GENERAL

By:

Phillip Rosario Assistant Attorney General

Juris No. 85059 110 Sherman Street Hartford, CT 06105 Tel: (860) 808-5400

Fax: (860) 808-5593

Dated: April 2, 2004

M. JANE BR

Attorney General of the State of Delaware

Olha N. Rybakoth Deputy Atterney General

Delaware Department of Justice

Fraud and Consumer Protection Division

820 N. French Street, 5th Floor Wilmington, Delaware 19801

Dated: March 31, 2004

ROBERT J. SPAGNOLETTI Corporation Counsel

DAVID M. RUBENSTEIN Deputy Corporation Counsel Public Safety Division

Bennett Rushkoff
BENNETT RUSHKOFF

Chief, Consumer and Trade Protection Section

GRANT G. MOY, JR.

Assistant Corporation Counsel
Office of the Corporation Counsel
441 Fourth Street, N.W., Suite 450 North
Washington, D.C. 20001
(202) 727-6337

Attorneys for the District of Columbia

Dated:

March 31, 2004

State of Florida Charles J. Crist, Jr.

Attorney General

By:

George LeMieux, FL Bar No. 016403 Deputy Attorney General Office of the Attorney General

PL-01, The Capitol Tallahassee, FL 32399

Tel: (850) 414-3300 Fax: (850) 487-2564

Dated: April 2, 2004

JOSEPH B. DOYLE Administrator, Governor's Office of Consumer Affairs

Anne S. Infinger

Director, Legal Division

Governor's Office of Consumer Affairs 2 Martin Luther King, Jr. Drive, Suite 356 Atlanta, GA 30334-4600

Dated: April 1, 2004

MARK E. RECKTENWALD, Director Department of Commerce and Consumer Affairs Office of Consumer Protection State of Hawaii

Michael J. S. Moriyama, Attorney

State of Hawaii

Office of Consumer Protection 235 S. Beretania St., Room 801 Honolulu, HI 96813-2419

808-586-2636

mmoriyama@dcca.hawaii.gov

808-586-2640 fax

Dated: March 31, 2004

Boise, Idaho

LAWRENCE G. WASDEN ATTORNEY GENERAL STATE OF IDAHO

Stephanie N. Guyon (ISB No. 5989)

Deputy Attorney General Consumer Protection Unit Office of the Attorney General Len B. Jordan Building 650 W. State St., Lower Level P. O. Box 83720

Boise, Idaho 83720-0010

Telephone: (208) 334-2424

(208) 334-2830 FAX:

sguyon@ag.state.id.us

LISA MADIGAN Attorney General of the State of Illinois

Deberah Hagan, Bureau Chief Office of the Illinois Attorney General Consumer Fraud Bureau 500 South Second Street Springfield, Illinois 62706

Karen Winberg-Jensen

Assistant Attorney General

Office of the Illinois Attorney General

Consumer Fraud Bureau 500 South Second Street Springfield, Illinois 62706

Dated: March 29, 2004

STEVE CARTER Indiana Attorney General Atty. No. 4150-64

By:

Terry Tolliver Deputy Attorney General Atty. No. 22556-49

Office of Attorney General Indiana Government Center South 302 W. Washington, 5th Floor Indianapolis, IN 46204 Telephone: (317) 233-3300

Dated march 23,2004

THOMAS J. MILLER Attorney General of the State of Iowa

William L. Brauch

Special Assistant Attorney General

Director-Consumer Protection Division

1305 E. Walnut Street Des Moines, IA 50319

Dated: 3-26-04

PHILL KLINE Attorney General of the State of Kansas

Stacy A. Jeffress

Assistant Attorney General Office of the Attorney General Consumer Protection Division 120 SW 10<sup>th</sup> Avenue, 2<sup>nd</sup> Floor Topeka, Kansas 66612-1597 (785) 296-3751 In the Matter of: Warner-Lambert LLC Assurance of Voluntary Compliance

Dated: April 1, 2004

GREGORY D. STUMBO

David R. Vandeventer Assistant Attorney General 1024 Capitol Center Drive Frankfort, KY 20601 (502) 696 5385

Dated: April 1, 2004

CHARLES C. FOTI, JR. Attorney General of the State of Louisiana

Isabel Wingerter

Assistant Attorney General

Office of the Louisiana Attorney General

1885 North 3rd Street Baton Rouge, LA 70802

Dated: March 30, 2004

G. STEVEN ROWE Attorney General of the State of Maine

LINDA J. CONTI

Assistant Attorney General
Office of the Attorney General

6 State House Station Augusta, ME 04333-0006 In the Matter of:

Warner-Lambert LLC Assurance

J. JOSEPH CURRAN, JR. ATTORNEY GENERAL OF MARYLAND

Dated: 04/01/04

By:

Ellen L. Kuhn

Assistant Attorney General Office of the Attorney General of Maryland 200 St. Paul Place, 16th Floor

Baltimore, Maryland 21202

Dated: 4/12/04

THOMAS F. REILLY

Attorney General

Commonwealth of Massachusetts

Jesse M. Caplan, BBO #645615

Assistant Attorney General

Consumer Protection and Antitrust Division

One Ashburton Place Boston, MA 02108

(617) 727-2200

Dated: April 1, 2004

MICHAEL A. COX

Attorney General of Michigan

Thomas P. Scallen (P22988)

Assistant Attorney General

Michigan Department of Attorney General

Cadillac Place

3030 West Grand Boulevard, Suite 10-200

Detroit, MI 48202

Dated:

MIKE HATCH Attorney General State of Minnesota

Ann M. Bildtsen

Assistant Attorney General 445 Minnesota Street, #1100 St. Paul, MN 55101-2128

Dated: April 2, 2004

JIM HOOD

Attorney General of the State of Mississippi

Deanne M. Mosley, MSB 9816

Special Assistant Attorney General

Office of the Mississippi Attorney General

P.O. Box 22947

Jackson, MS 39225

Phone: 601-359-4230

Dated: 4/9/04

JEREMIAH W. (JAY) NIXON Attorney General of the State of Missouri

Stewart Freilich

Assistant Attorney General

P.O. Box 899

Jefferson City, MO 65102

Dated: April 2nd, 2004

Cort Jersen

State of Montana

Consumer Protection Office

1219 8th Ave

Helena, MT 59620

Dated: 4-1-04

STATE OF NEBRASKA, ex rel., Jon Bruning, Attorney General

BY: JON BRUNING, #20351 Attorney General

BY: Cestully

Leslie C. Levy, #20673 ( Assistant Attorney General 2115 State Capitol Lincoln, NE 68509-8920

Tel.: (402) 471-2811

	3/31/04		
Dated:			

BRIAN SANDOVAL Attorney General

By: Tracey J. Brierly

Deputy Attorney General Nevada Bar No. 006237

555 E. Washington Ave., #3900

Las Vegas, NV 89101

(702) 486-3128

In the Matter of:

Warner-Lambert LLC Assurance

PETER W. HEED

Attorney General of the State of New Hampshire

M. Kustin Spelh

Dated

3/26/04

M. Kristin Spath

Senior Assistant Attorney General

Bureau Chief

Consumer Protection and Antitrust Bureau

Office of the New Hampshire Attorney General

33 Capitol Street

Concord, NH 03301

PETER C. HARVEY ATTORNEY GENERAL OF NEW JERSEY

By: Sunil Raval

Deputy Attorney General

In the Matter of: Warner-Lambert LLC Assurance

Dated: April 2, 2004

PETER C. HARVEY ATTORNEY GENERAL OF THE STATE OF NEW JERSEY

Sunil Raval

Deputy Attorney General

Division of Law 124 Halsey Street- 5<sup>th</sup> Floor P.O. Box 45029 Newark, New Jersey 07101 (973) 648-4741

Dated:

Patricia A. Madrid

Attorney General of the State of New Mexico

Donald C. Trigg

Assistant Attorney General

Patricia C. Madrid

Office of the New Mexico Attorney General

407 Galisteo Street

Santa Fe, New Mexico 87504

Dated: April 2, 2004

ELIOT SPITZER

Attorney General of the State of New York

Shirley Stark

Assistant Attorney General

Office of the New York Attorney General

120 Broadway

New York, NY 10271

Dated: March 30, 2004

ROY COOPER

Attorney General of the State of North Carolina

Parbasa 9. Show

Barbara A. Shaw Assistant Attorney General Office of the North Carolina Attorney General 114 W. Edenton Street Raleigh, NC 27602

Dated: March 23, 2004

State of North Dakota Wayne Stenehjem Attorney General

By:

Parrell D. Grossman, ID No. 04684

Assistant Attorney General

Director, Consumer Protection &

Antitrust Div.

Office of Attorney General

PO Box 1054

Bismarck, ND 58502-1054

(701)328-5570 (Telephone)

(701)328-5568 (Fax)

Dated: April 2, 2004

JIM PETRO

Attorney General of the State of Ohio

Michael S. Ziegler Assistant Attorney General

Office of the Ohio Attorney General

Consumer Protection Section

30 East Broad Street. 14th Floor

Columbus, Ohio 43215

In the Matter of:

Warner-Lambert LLC Assurance

Dated: 4/01/04

W.A. DREW EDMONDSON Attorney General of the State of Oklahoma

Twheele

one F. Wheeler

Assistant Attorney General Office of the Attorney General 4545 N. Lincoln Blvd., Suite 260

Oklahoma City, Oklahoma 73105

(405) 521-4274

Dated March 29, 2004

HARDY MYERS

Attorney General of the State of Oregon

David A. Hart

Assistant Attorney General

Office of the Oregon Attorney General 1162 Court Street, N.E. Salem, Or. 97301-4096

Dated: April 2, 2004

GERALD J. PAPPERT

Attorney General, Commonwealth of Pennsylvania

Leslie M. Grey

Deputy Attorney General

Commonwealth of Pennsylvania

Office of Attorney General

Bureau of Consumer Protection, Erie Regional Office

1001 State Street, Suite 1009

Erie, PA 16501

Dated: April 9, 2004

PATRICK C. LYNCH Attorney General for the State of Rhode Island

Rebecca Tedford Partington Assistant Attorney General Department of Attorney General 150 South Main St. Providence, RI 02903 (401) 274-4400 ext. 2303 Rpartington@riag.state.ri.us

> HENRY D. McMASTER Attorney General of the State of South Carolina

C. HAVIRD JONES, JR.

Senior Assistant Attorney General

Office of the Attorney General

P. O. Box 11549

Columbia, SC 29211

(803) 734-3680

March 26, 2004.

Dated: April 2, 2004

LARRY LONG Attorney General of the State of South Dakota

Paul Cremer

Assistant Attorney General Office of the South Dakota Attorney General 500 East Capitol Avenue

Pierre, SD 57501-5070 (605) 773-3215

pld.pc Warner-Lambert LLC Assurance(jmm)

Dated: 4/02/04

PAUL G. SUMMERS State of Tennessee Attorney General and Reporter

MEREDITH DEVAULT, BPR No. 9157

Senior Counsel

Consumer Advocate and Protection Division

Office of the Attorney General

P.O. Box 20207

Nashville, Tennessee 37202-0207

(615) 532-2578, FAX: (615) 532-2910

Dated: April 2, 2004

Attorney General of the State of Texas GREGG ABBOTT

Joyce Wein Iliya

Assistant Attorney General

Consumer Protection and Public Health

Office of the Attorney General 1600 Pacific Avenue, Suite 1700

Dallas, Texas 75201

Telephone: (214) 969-7639, ext. 111

Facsimile: (214) 969-7615 State Bar No. 00784319

Dated: 4-13-04

MARK L. SHURTLEFF Utah Attorney General

Jeffre 8. Buckner

Assistant Attorney General Utah Attorney General's Office 160 East 300 South, 5th Floor

P.O. Box 140872

Salt Lake City, Utah 84114-0872

Dated: April 2, 2004

WILLIAM H. SORRELL Attorney General of the State of Vermont

Julie Brill Assistant Attorney General Office of the Vermont Attorney General 109 State Street Montpelier, VT 05609-1001

## JERRY W. KILGORE, Attorney General of Virginia

In the Matter of: Warner-Lambert LLC Assurance

Dated: April 2, 2004

JERRY W. KILGORE Attorney General of the Commonwealth of Virginia

COURTNEY M. MALVEAUX Assistant Attorney General

Office of the Attorney General of Virginia

900 East Main Street Richmond, Virginia 23219

Dated: March 30, 2004

BY:

CHRISTINE O. GREGOIRE Attorney General of Washington

ROBERT A. LIPSON, WSBA #11889

Assistant Attorney General

Attorneys for State of Washington

900 Fourth Avenue, Suite 2000

Seattle, WA 98164-1012

206.464.7744

Dated:

DARRELL V. McGRAW, JR. ATTORNEY GENERAL

Jill L. Miles

Deput Attorney General State Bar ID No. 4671

Consumer Protection/Antitrust Division

Post Office Box 1789

Charleston, West Virginia 25326-1789

Dated: April 2, 2004

PEGGY A. LAUTENSCHLAGER Attorney General

CYNTHIA R. HIRSCH Assistant Attorney General State Bar #1012870

Attorneys for State of Wisconsin

Wisconsin Department of Justice Post Office Box 7857 Madison, Wisconsin 53707-7857 (608) 266-3861

March 31, 2004

Patrick J. Crank

Attorney General of the State of Wyoming 123 State Capitol

Cheyenne, WY 82002

1	EXHIBIT A				
2					
3					
4	IN THE CIRCUIT COURT OF THE STATE OF OREGON				
5	FOR THE COUNTY OF MARION				
6	IN THE MATTER OF WARNER- Case No. xxxxxxxxxx				
7	LAMBERT COMPANY, LLC.  ORDER GOVERNING THE				
8	ADMINISTRATION OF MULTISTATE GRAN AND ADVERTISING PROGRAM	T			
9					
10	THIS MATTER having come before the Court on the stipulation of the parties through an				
11	Assurance of Voluntary Compliance, the Court having reviewed the pleadings and otherwise				
12	being fully advised;				
13	IT IS HEREBY ORDERED				
14	1. The Settlement Accounts				
15	1.1 This Order governs the creation and administration of the Settlement Account, the				
16 17	Prescriber and Consumer Education Subaccount, the Advertising Subaccount and the Evaluation				
18	Subaccount (hereinafter collectively "the Accounts") established pursuant to the Assurance of				
19	Voluntary Compliance entered into by Warner-Lambert Company LLC ("Warner Lambert") and				
20	the Signatory Attorneys General <sup>1</sup> .				
21					
22 23 24 25 26	The Attorneys General of the states of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin and Wyoming. For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys General," such designation, as it pertains to Connecticut, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Assurance of Voluntary Compliance pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110i, acting by and through his counsel, Richard Blumenthal, Attorney General for the				

2	the Assurance of Voluntary Compliance, the Oregon Attorney General, on behalf of the				
3	Multistate Working Group ("MSWG"), shall deposit twenty-eight million U.S. dollars				
4	(\$28,000,000.00) into the Settlement Account established pursuant to Paragraph 20 of the				
5	Assurance, and thereafter transferred into three interest bearing subaccounts: The Advertising				
6	Subaccount, the Prescriber and Consumer Education Subaccount and the Evaluation Subaccount.				
7	The Oregon Attorney General shall hold in trust all funds in the Accounts for the sole benefit of				
8	the MSWG and the purposes delineated in the Assurance for such funds. Such funds and the				
9	the M5 W6 and the purposes defineded in the Assurance for such funds. Such funds and the				
10	interest generated therefrom shall not be commingled with other funds. Distributions from the				
11	Accounts shall be made only as permitted under this Order. Nothing herein shall prohibit the				
12	addition of funds to the Accounts, provided that such additional sums remain subject to this				
13	Order.				
14	2. The Prescriber and Consumer Education Subaccount				
15	2.1 Twenty-one million U.S. dollars (\$21,000,000.00) shall be paid from the				
16	2.1 Twenty-one minion 0.3. donars (\$21,000,000.00) shall be paid from the				
17	Settlement Account for use by the MSWG to develop the Prescriber and Consumer Education				
18	Program. The fund subaccount that shall finance the Prescriber and Consumer Education				
19	Program shall be known as the Prescriber and Consumer Education Subaccount.				
20					
21	State of Connecticut. The chief legal officer of the District of Columbia is the Corporation Counsel, who for uniformity shall also be referred to as "Attorney General." With regard to				
22	Georgia, the Administrator of the Fair Business Practices Act, appointed pursuant to O.C.G.A. Section 10-1-395, is statutorily authorized to undertake consumer protection functions, including				
23	the acceptance of Assurances of Voluntary Compliance, for the State of Georgia. The term "Attorneys General" as used herein, as it pertains to Georgia, refers to the Administrator of the				
24	Fair Business Practices Act. With regard to Hawaii, Hawaii is represented by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but				
25	which is statutorily authorized to represent the State of Hawaii in consumer protection actions.				
26	Hereafter, when the entire group is referred to as the "States" or "Attorneys general," such designation as it pertains to Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection. For Montana, the acting agency is the Consumer Protection Office.				

Within 10 days of receipt of the settlement fund established by paragraph 20 of

1.2

2.2 Distributions from the Prescriber and Consumer Education Subaccount shall be
made at the discretion of a Special Committee composed of the Attorneys General (or their
authorized designees) that comprise the Neurontin Multistate Executive Committee2 (MSEC)
and two Attorneys General (or their authorized designees) from the remaining members of the
MSWG which shall be selected on a biannual rotating basis, in the first instance by the Attorneys
General of the MSEC, and thereafter by the Attorneys General represented on the Special
Committee.

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- 2.3 The Attorneys General that comprise the MSEC have selected the Attorneys General of California and North Carolina to serve on the Special Committee for the first two years.
- 12 2.4 The Special Committee may authorize expenditures in any amount necessary to
  13 exhaust the fund within six years. However, the Special Committee has discretion to make
  14 distributions for an additional period if additional time is necessary to identify qualified grant
  15 recipients.
  - 2.5 The initial distributions from the Prescriber and Consumer Education Subaccount shall be made within eighteen months from the Effective Date of the Assurance.
  - 2.6 Distributions from the Prescriber and Consumer Education Subaccount may be made and approved, and distributions used, only for the purpose of funding programs designed to educate prescribers and/or consumers relating to drug information, drug marketing, and the conditions for which drugs are prescribed, as authorized by Paragraphs 27-29 of the Assurance and by this Order.

<sup>2</sup> Florida, New York, Ohio, Oregon, Texas and Vermont

2.7 The Special Committee shall give special consideration to programs that (i) relate to medical and psychological conditions for which Neurontin was prescribed and/or to classes of drugs used to treat these conditions; (ii) can demonstrate through objective criteria that their proposal is likely to have a measurable impact on prescribers' access to relevant information about drugs prescribed or on the health and/or welfare of consumers; (iii) provide national and regional benefits as opposed to programs that benefit individual states.

Q

- 2.8 The Special Committee shall strive to make distributions equitably to programs throughout the MSWG states. However, this consideration will be secondary to the considerations set forth in paragraph 2.7.
- 2.9 Distributions from the Prescriber and Consumer Education Subaccount may be made to the following offices, agencies, organizations, and institutions located within the MSWG states: individual states or a group of states or other governmental entities; academic institutions; or not-for-profit organizations that have current section 501(c)(3) status from the Internal Revenue Service and have expertise and experience in health-related or consumer protection issues; provided that applications for distribution from such not-for-profit corporations or entities are accompanied by written support for their request from a MSWG Attorney General of a state in which the entity operates.
- 2.10 Recipients of grants shall use grant monies only to fund activities that have not been funded previously or which, but for the receipt of the grant from the Prescriber and Consumer Education Program, would not be fully funded. If an activity has been previously funded, the grant recipient shall not use its grant from the Prescriber and Consumer Education Program to supplant existing funding and shall only use it to fund shortfalls in existing funding.

1	2.11	The Special Committee may consider the following factors, in addition to those			
	considerations described above and others which the Special Committee deems relevant, in				
2	acting upon a request for distribution:				
3	(a)	the intended purpose of the grant;			
4	(b)	competing requests for grant funding;			
5	(c)	the financial ability of the intended grant recipient to obtain the requested goods,			
6		services or funding assistance without grant funds;			
7	(d)	the anticipated public benefit to be served by approving the grant;			
	(e) the ability of the Special Committee to audit the use of the grant to ensure that				
8	grant is used solely for purposes authorized hereunder;				
9	(f)	the amount of previous grants made to a particular grant recipient and the use of			
10	previous grants in accordance with the terms of the Assurance and this Order;				
11	(g) the ability of the grant recipient to provide the Special Committee with a r				
12	regarding the actual results obtained as a result of any grant; and,				
13	(h)	the academic institution or not-for-profit entity (or its principals if the entity has			
14		not existed for three years) has previously successfully operated programs eligible			
		for funding by the Prescriber and Consumer Education Program.			
15	2.12	The Special Committee may attach written conditions to the award of any grant			
16	from the Prescriber and Consumer Education Program.				
17	2.13	The Special Committee shall require each grant recipient, prior to receiving any			
18	grant, to agre	e in writing to:			
19	(a)	comply with each and every order of the Court in connection with the Prescriber			
20		and Consumer Education Program and the grant received;			
	(b)	provide quarterly reports and a final report specifying how grant monies were			
21		used and how the grant furthered the purposes of prescriber and consumer			
22		education;			
23	(c)	permit the Special Committee or its designee to conduct an unrestricted audit,			
24		review, examination or inquiry concerning the grant and the use of grant funds,			
25		and cooperate with any such inquiry by the Special Committee or its designee;			
26 (d) vigilantly safeguard the monies granted hereunder and maintain finance		vigilantly safeguard the monies granted hereunder and maintain financial controls			
		sufficient to protect such monies and ensure that the use of monies fully comparts			

1		with the recipient's application for grant, and provide a detailed written		
		description of such financial controls upon request by the Special Committee;		
	2 (e) use the grant monies solely for the purposes set forth in the grant application			
3		return to the Prescriber and Consumer Education Program, within ten days of the		
4		conclusion of the grant period, any monies not so used. The Special Committee		
5		may designate, and require completion of, forms to satisfy the requirements of		
6		this paragraph;		
7	(f)	certify, at the end of the conclusion of the grant period, that the grantee has		
	complied with the contractual provisions described in Section 2.17, below; and			
8	(g)	comply with any written condition(s) that the Special Committee has attached to		
9		the grant.		
10	2.14	The Special Committee shall entertain requests for distribution from the		
11	Prescriber and Consumer Education Subaccount.			
12	2.15	All requests for distribution shall be made in writing on a form approved by the		
13	Special Committee, which the Special Committee shall provide to each Attorney General and			
14	make available to others upon request.			
	2.16	A majority vote of the members of the Special Committee shall be required for		
15	any distribution from the Prescriber and Consumer Education Subaccount. The decisions of the			
16	Special Committee shall be final and non-appealable.			
17	2.17	The Special Committee shall require in any contract with a grantee of the		
18	Prescriber and Consumer Education Program that the grantee possesses, with respect to any			
19	representation made in a public communication produced in connection with said grant,			
20	substantial evidence or substantial clinical experience that substantiates the representation			
21	2.18	When an application for a grant from the Prescriber and Consumer Education		
	Program is m	ade by an Attorney General who is then a member of the Special Committee or by a		
22	governmental agency within the same State as a member of the Special Committee, or by a non-			
23	profit entity who submits support from said Attorney General who is a member of the Special			
24	Committee, the Attorney General shall not participate in the discussion pertaining to the			
25	application ar	nd shall not vote on the grant application.		
26	2.19	The Special Committee may, upon vote by six members of the Special		
	Committee,	retain experts and other vendors from the monies in the Prescriber and Consumer		

Education Subaccount to assist in developing the criteria for grant applications as well as in reviewing grant applications. The Special Committee may, upon vote by six members of the Special Committee, also designate a person or entity to administer or help administer the Prescriber and Consumer Education Subaccount on an annual, renewable basis. Such designee may, for instance, provide assistance in evaluating the applications, provide notice of the application process and accept applications for distribution on behalf of the Special Committee, and assist in preparation of the Special Committee's annual report described herein.

2.20 The Special Committee also may authorize payments from the Prescriber and Consumer Education Subaccount to help defray reasonable administrative costs in connection with the Prescriber and Consumer Education Program (whether incurred by the Special Committee or by its designee, if any), which annual payment may be made from the interest earned on the Prescriber and Consumer Education Subaccount. The administrative fee, if any, shall be verified by the Special Committee as reasonable and appropriate for administrative costs actually incurred.

2.21 No individual State shall have any claim to the funds in the Prescriber and Consumer Education Subaccount. Distributions from the foregoing Subaccount shall be made at the discretion of the Special Committee and solely for the purposes outlined in the Assurance and this Order.

## 3. The Advertising Subaccount

3.1 Six million U.S. dollars (\$6,000,000.00), shall be paid from the Settlement Account for use by the MSEC to develop the National Advertising Program on behalf of the MSWG. The fund subaccount that shall finance the National Advertising Program shall be known as the Advertising Subaccount. Such fund shall be administered by the MSEC.

3.2 The National Advertising Program shall provide information to prescribers regarding Neurontin and other drugs in the same therapeutic class, including, but not limited to, by placing advertisements in medical journals.

1	3.3	The MSEC may retain experts and other vendors, including advertising agencies,			
2	from the monies in the Advertising Subaccount to assist in the drafting, design and				
3	implementation of the National Advertising Program on behalf of the MSWG.				
4	3.4	Any advertisement or other public communication regarding Neurontin prepared			
5	in connection	with the National Advertising Program shall not be misleading or lacking in fair			
6	balance, as defined in 21 CFR §202.1.				
7	3.5	At the conclusion of the National Advertising Program as determined by the			
9	MSEC, any portion of the monies provided for in Paragraph 3.1 of this Order that are not				
10	expended in the National Advertising Program, pursuant to Paragraphs 3.2 and 3.3, shall be				
11	transferred to the Prescriber and Consumer Education Subaccount.				
12	3.6	No individual State shall have any claim to the funds in the Advertising			
13	Subaccount.	Distributions from the foregoing subaccount shall be made at the discretion of the			
14	MSEC, and s	olely for the purposes outlined in this Assurance.			
15 16	4. The I	Evaluation Subaccount			
17	4.1	One million U.S. dollars (\$1,000,000.00) shall be paid from the Settlement			
18	Account into	the Evaluation Subaccount, created for the purpose of evaluating the effectiveness			
19	of the National Advertising Program and the Prescriber and Consumer Education Program, and				
20	of grantees' compliance with the requirements of the Prescriber and Consumer Education				
21					

Committee may retain an expert or experts from the Evaluation Subaccount to conduct evaluations of the effectiveness of the National Advertising Program and the Prescriber and Consumer Education Program.

Program. The Evaluation Subaccount shall be administered by the Special Committee. No

individual State shall have any claim to the funds in the Evaluation Subaccount. The Special

1		4.2	Any portion of the monies provided for in Paragraph 4.1 of this Order that are not		
2	expended in the Evaluation Program shall be transferred to the Prescriber and Consumer				
3	Education Subaccount.				
4	5. Reporting				
5		5.1			
6	shall be made available to the MSWG, concerning the Prescriber and Consumer Education				
7	Subaccount and the activities funded thereby. Such annual report shall include a report on the				
92	follo	wing:			
8		(a)	the amount of money in the Prescriber and Consumer Education Subaccount, a		
9			general description of how the funds are held, and the amount of interest		
10			generated during the preceding year,		
11		(b)	the composition of the Special Committee, including the Attorneys General		
12	designated to replace the members of the Special Committee that change				
13	annually; and,				
		(c)	the requests for distribution from the Prescriber and Consumer Education		
14	Subaccount and the actions of the Special Committee upon such requests.		Subaccount and the actions of the Special Committee upon such requests.		
15		5.2	Not less than once each year, the Special Committee shall compile a report,		
16	which shall be made available to the MSWG, concerning the Advertising Subaccount and the				
17	Evaluation Subaccount and the activities funded thereby. Such annual report shall include a				
18	report on the following:				
19		(a)	the amount of money in the accounts, a general description of how the funds are		
20	held, and the amount of interest generated during the preceding year; and,				
		(b)	the distributions from the accounts and the activities which the distributions		
21			funded.		
22	6.	Gene	ral Provisions		
23		6.1	This Order is intended to define and determine the administration of the accounts		
24	created under the Assurance of Voluntary Compliance In the Matter of Warner-Lambert LLC.				
25	6.2 All capitalized terms in this Order that are defined in the Assurance shall have the		All capitalized terms in this Order that are defined in the Assurance shall have the		
26	same meaning in this Order as set forth in the Assurance.				

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1	7. Continuing Jurisdiction					
	The Oregon court shall maintain jurisdiction over this matter to alter or amend this Orde					
2	as justice so requires. Every Signatory Attorney General to the Assurance shall be permitted to					
3	apply to the Oregon court to alter or amend this Order as justice so requires, and to otherwise					
4	enforce this Order.					
5	IT IS SO ORDERED this	day of	, 2004.			
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8	Submitted by: David A. Hart	Circuit Court Jud	lge			
9	Assistant Attorney Of Attorneys for P					
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